DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

Merz Dental GmbH
c/o Richard G. Hunter, MS
Regulatory Affairs Consultant
Washington Regulatory Consultants
5616 Mariola PL NE
Albuquerque, NM 87111

Re: K140758
Trade/Device Name: M-PM-Disc (Pink)
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: II
Product Codes: EBI, EBG
Dated: August 5, 2014
Received: August 12, 2014

Dear Mr. Hunter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known):

Device Name: M-PM-Disc (Pink)

Indications for Use:

Device for fabrication of dental bases for removable dentures.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Merz Dental GmbH M-PM-Disc (Pink)

Submitter

Company Name:	Merz Dental GmbH
Address:	Eetzweg 20 Lutjenburg, Germany D-24321
Contact Name:	Dr. Med. Claudia Bobrowski
Telephone No.	(011) 43 81/4 03-4 11
Fax No.	(011) 43 81/4 09-1 07
e-mail:	Claudia.bobrowski@merz-dental.de

Date of Summary: August 5, 2014

Device Name

Proprietary name: M-PM-Disc (Pink)

Common name: Denture Base

Classification name: Resin, Denture, Relining, Repairing, Rebasing

Predicate Devices: Denture Resins ((e.g. Promolux)
For Casting of Denture Bases
K130076
Merz Dental GmbH

M-PM-Disc (Tooth Colored)
For Fabrication of Crowns and Bridges
K071548
Merz Dental GmbH

Intended Use

Merz Dental GmbH M-PM-Disc (Pink) is a device for fabrication of dental bases for removable dentures.

Device Description

The Merz Dental GmbH M-PM-Disc (Pink) is a disc composed of solid polymethylmethacrylate (PMMA) in sizes ranging from 90 x15 mm to 114.8 x 25 mm.

The PMMA is a highly cross-linked material manufactured by Merz Dental GmbH under a proprietary process and branded as OMP-N. MP-M-Disc (Pink) is composed of > 95 % PMMA with less than 2% MMA residual. Additional components are coloring agents that include: titanium dioxide, iron oxide yellow, iron oxide black, iron oxide red, azo-condensation pigment red, and rayon fibers for veined shades.

Technological Characteristics

The Merz Dental GmbH OMP-N PMMA has been tested according to the following standards. The results are presented in the table below.

Physical Parameter*	Standard (ISO)	OMP-N
Flexural strength (MPa)	10477	93.4
Water sorption (ug/mm^3)	10477	26.5
Water solubility (ug/mm^3)	10477	0.2
Flexural modulus (MPa)	20795-1	2678±74
Flexural strength (MPa)	20795-1	90 ± 1.5
Residual methyl methacrylate (Mass % Fraction)	20795-1	1.14
Fracture Toughness (Kmax) (MPa m^1/2	20795-1	1.41 +- 0.04
Fracture work (Wf) (J/m2)	20795-1	202 +- 13

Substantial Equivalence

M-PM-Disc (Pink) is substantially equivalent to predicate denture base resin systems, such as the Merz Dental GmbH Denture Base Resins one of which is the hot-curing Promolux and

Merz Dental GmbH M-PM Disc (Tooth Colored) for fabrication of crowns and bridges. The three devices are compared in the table below.

Device	**M-PM-Disc (Pink)**	**Promolux (Pink)**	**M-PM-Disc (Tooth Colored)**
Indications	Device for fabrication of denture bases	Resin system for fabrication of denture bases	Device for fabrication of crowns and bridges
Material Composition	OMP-N PMMA	PMMA	OMP-N PMMA
Material Form	Solid Disc	Powder and Liquid	Solid Disc
Fabrication	Milling	Casting	Milling
Clearance	Subject of Application	K130076	K071548
Manufacturer	Merz Dental, GmbH	Merz Dental, GmbH	Merz Dental, GmbH

As shown in the table, both the M-PM-Disc (Pink) and Promolux are composed of polymethylmethacrylate (PMMA) with pink colorants, and are indicated for the fabrication of dental bases. In addition the M-PM-Disc (Pink) has the identical material composition, method of manufacture, and final fabrication method as the Merz Dental GmbH M-PM-Disc (Tooth Colored), a device for fabrication of crowns and bridges. Both M-PM-Disc (Pink) and M-PM-Disc (Tooth Colored) are solid PMMA discs composed of highly cross-linked PMMA (OMP-N), and milled at the dental lab into the final shape of the prosthesis.

Merz Dental has tested OMP-N for physical/chemical properties and biocompatibility. The PMMA material met the applicable standards for physical/chemical properties (ISO 10477 and 20795-1), and was nontoxic and non-sensitizing in the *in vitro* cytotoxicity test system (ISO 10993-5) and the guinea pig sensitization model (ISO 10993-10.2).

Summary

Merz Dental GmbH M-PM-Disc (Pink) has similar indications, composition, manufacturing methods and biocompatibility as the predicate devices. Therefore Merz Dental considers the M-PM-Disc (Pink) to substantially equivalent to the predicate devices.